REMARKS

In the aforesaid Office Action, claims 26 was rejected under 35 USC § 112, second paragraph, claims 26, 28-29, 34 and 35 were rejected under 35 USC § 102(b) as being anticipated by Wang et al. (US 5,556,383), and claims 30-33, 36 and 37 were rejected under 35 USC § 103(a) as being unpatentable over Wang et al. alone. Claims 26 and 28-37 are pending.

The Examiner rejected claim 26 under 35 USC § 112, second paragraph, stating that it is not clear if "the inner diameter of the balloon mold" is the same as the nominal outer diameter of the balloon, and "an inflation pressure required to fill the blow-molded inflated volume at an ambient temperature" is the same as the nominal pressure of the balloon.

The inner diameter of the balloon mold is the same as the nominal outer diameter of the balloon absent any radial shrinkage (or growth) of the balloon inflated to the nominal pressure, and the inflation pressure required to fill the blow-molded inflated volume at an ambient temperature is the same as the nominal pressure of the balloon, as discussed in more detail below.

Specifically, the radial shrinkage of the balloon should be understood to refer to the amount by which the blow molded outer diameter of the balloon shrinks. Specifically, blow-molded balloons have an inflated shape corresponding to the inner shape of the balloon mold used to blow-mold the balloon (in the deflated state, the excess balloon material is typically formed into wings wrapped around the catheter to form a

low profile configuration, which unwrap as the balloon inflates). As a result, balloons are understood to have an inflated outer diameter (commonly referred to as the "nominal" outer diameter) resulting from the volume of the blow-molded balloon being filled with inflation fluid at an inflation pressure which is therefore commonly referred to as the "nominal" pressure, without stretching/distending the blow-molded wall beyond the nominal outer diameter which results from just filling the blow-molded volume of the balloon. In the absence of "radial shrinkage" as defined in Applicant's claims, just filling the blow-molded volume of the balloon with inflation fluid would result in an inflated outer diameter equal to the inner diameter of the balloon mold. Consequently, the "radial shrinkage" of the balloon set forth in Applicant's claim 26 should be understood to refer to the amount by which the inflated outer diameter of the balloon at the inflation pressure required to just fill the blow-molded volume of the balloon as part of a catheter is less than the inner diameter of the balloon mold used to form the balloon.

The Examiner states that Wang et al. discloses balloons (examples 1-2) having radial distention % or shrinkage % less than 10% as measured by a difference from the inflated outer diameters of the balloons/nominal diameters (2.25mm in example 1; 3mm in example 2) and the inner diameters of the molds/nominal outside diameters of the balloons at ambient temperature (2.25mm in example 1; 3mm in example 2), when inflated to a nominal pressure.

However, as set forth by the Examiner, the Examiner is comparing the nominal diameter of the balloon to itself (i.e., the Examiner compares the "nominal diameter" of the balloon to the "nominal outside diameter" of the balloon). Although the Examiner

also is comparing the inflated outer diameter of the balloon/nominal diameter to the inner diameter of the mold, as set forth by the Examiner the balloon of Wang examples 1 and 2 has no radial shrinkage (the balloon OD inflated at nominal pressure being equal to the mold inner diameter). In contrast, the embodiment of Applicant's claim 26 requires that the balloon has a radial shrinkage. Similarly, claim 26 explicitly defines the radial shrinkage as the difference between the inner diameter of the balloon mold used to blow-mold the balloon and the inflated outer diameter of the balloon at an inflation pressure required to fill the blow-molded inflated volume at an ambient temperature as part of a catheter system after exposure to a shrinking treatment which causes the radial shrinkage, which is not disclosed or suggested by Wang et al. Therefore, although Wang et al. discloses that a 3.0 mm balloon is formed in a 3.0 mm size mold (see Wang et al. example 2), there is no teaching or suggestion in Wang et al. of the issue of minimizing radial shrinkage of a balloon heat-set using a heating member after exposure to a shrinking treatment which causes the balloon diameter to radially shrink.

Claim 26 is amended to set forth that the balloon has a radial shrinkage of greater than 0%, support for which can be found in Applicant's specification at paragraph [0032], which discloses an embodiment in which the balloon has a radial shrinkage or a measurable change in the outer diameter, i.e., "the formed balloon has a minimal radial shrinkage (for example, as measured by the % change in the outer diameter of the working length of an inflated balloon as part of a catheter system versus as formed after the present process)."

Applicant respectfully requests reconsideration, and issuance of a timely Notice of Allowance.

Respectfully submitted,

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